

Patent Application No.: 09/340,391

they contain. No new matter is added. Attached is a clean copy setting forth the status of the claims after the above amendments.

THE REJECTIONS UNDER 35 U.S.C. 112, SECOND PARAGRAPH

The Office Action rejects claims 1- 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office Action asserts that the terms "acceptable," "derivative" and "inhibitor" are indefinite. In response, Applicant respectfully submit that one of ordinary skill in the reading the claims in light of the supporting written description would readily understand the meaning of these terms. Thus, Applicant respectfully requests reconsideration and withdrawal of this aspect of the rejection.

The Office Action asserts that "Phase I and/or Phase II" in claims 2 and 8 is indefinite. In addition, the Office Action states that " monocyclic, carbocyclic ring structure" in claims 3 and 9 are indefinite. In response, Applicant has cancelled these claims soley in an effort to advance prosecution.

The Office Action states that "MGK" is an abbreviation that should be spelled out in the claims. In response, Applicant respectfully submits that MGK is a well known abbreviation for the commercial company, McLaughlin Gormley King Company. Applicant has amended the specification to clarify that MGK 264 is a trade name for N-octyl bicycloheptene dicarboximide. One of skill in the art reading the claims in view of the amended specification would readiliy

Patent Application No.: 09/340,391

understand the meaning of MGK 264. This aspect of the rejection is overcome.

The Office Action states that parenthetical in "aldehyde C16 (pure)" is unclear. In response, Applicant has deleted "(pure)". This aspect of the rejection is overcome.

The Office Action states that "metabolites of trans-anethole" is ambiguous. In response, Applicant has deleted "metabolites of" to overcome this aspect of the rejection.

The Office Action states that "synergist" should be identified in the claims. In response, Applicant has amended the claims to overcome this aspect of the rejection.

The Office Action states that the Examiner is not familiar with PD 98059. In response, Applicant has amended the specification and claims to clarify that PD 98059 is well known for representing 2'-amino-3'-methoxyflavone. This aspect of the rejection is overcome.

THE REJECTIONS UNDER 35 U.S.C. 112, FIRST PARAGRAPH

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The Office Action states:

The claims are beyond the scope of the specification: one of ordinary skill in the art would not know which pests, how much of each active synergist and inhibitor, and which active, synergist, inhibitor should be used in order to effect control, and to provide compositions for control. One would not know which drugs are Phase I or phase II studies.

Office Action at page 3. Applicant respectfully traverses this rejection.

Patent Application No.: 09/340,391

It must be kept in mind that the test for enablement is whether one skilled in the art can make or use the claimed invention without undue experimentation in light of the teachings in the specification coupled with the information known in the art. United States v. Teletronics, Inc., 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). As such, a patent application need not teach, and preferably omits, what is well known in the art. See In re Buchner, 18 U.S.P.Q.2d 1331 (Fed. Cir. 1991). Further, a specification is enabling even though some experimentation is necessary, as long as the amount of the experimentation is not unduly extensive. Utter v. Hiraga, 6 U.S.P.Q.2d 1709, 1714 (Fed. Cir. 1988). Thus, in describing the claimed invention, Applicants are not required to explain every detail since they are speaking to those of ordinary skill in the art. In re Howarth, 210 U.S.P.Q. 690, 691 (C.C.P.A. 1981).

Furthermore, a rejection based on a lack of enablement cannot be maintained solely on the basis that the number of recited compounds encompassed by the claimed methods exceeds those specifically disclosed in the specification or that an inadequate number of specific examples is presented. There is no "magical" or predetermined relationship between the number of representative examples and the breadth of the claims. In fact, no working examples are necessary. In re Borkowski, 164 U.S.P.Q. 642 (C.C.P.A. 1970). When a broad term is supported by the specification, an Applicant should not be denied the use of the term merely because it is broad. In re Grier, 144 U.S.P.Q. 654 (C.C.P.A. 1965). As exemplified in re Angstadt:

Appellants have apparently not disclosed every catalyst which will work; they have apparently not disclosed every catalyst which will not work. The question, then, is whether in an unpredictable art, section 112 requires disclosure of a test with every species covered by a claim. To require such a complete disclosure would

Patent Application No.: 09/340,391

apparently necessitate a patent application or applications with "thousands" of examples or the disclosure of "thousands" of catalysts along with information as to whether each exhibits catalytic behavior resulting in the production of hydroperoxides. More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid "literal" infringement of such claims by merely finding another analogous catalyst complex which could be used in "forming hydroperoxides."

In re Angstadt, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976). Applicants' statements in the specification cannot be questioned (i.e., they must be accepted as true) unless contrary facts (evidence or scientific reasoning) can be presented.

Applicants respectfully submit that the Examples describe assays/testing protocols that are recognized in the art and thereby enable one skilled in the art to make and use the pesticidal compositions recited in the claims *without undue experimentation*. Indeed the disclosed assays/protocols may be used to validate the effects of the recited compositions and methods for using them. Using the disclosed procedures, a skilled artisan would be enabled to readily and systematically validate the pesticidal utility/activity of compositions required in by the claims. Indeed, questions of efficacy and safety of the recited compositions and methods are more appropriately addressed by other governmental agencies, i.e., the U.S. Environmental Protection Agency. The degree of investigation described above is not beyond the skill of practitioners in the art, especially in view of the disclosure in the specification. The specification need not eliminate all experimentation. Such routine validation is not beyond the level of skill for skilled

Patent Application No.: 09/340,391

practitioners in the pharmaceutical arts and does not constitute undue experimentation. See *Ex parte Forman*, 230 USPQ 546 (BPAI 1986). In other words, Applicants respectfully submit that at least the Example provide specific guideposts that point the public to use the claimed pesticidal compositions and demonstrate that one skilled in the art could readily use, without undue experimentation, the claimed invention to develop specific compositions for use in treating specific pests utilizing only the information disclosed in the specification and knowledge that was readily available in the art at the time of the effective filing date of the present application. The Examiner has not presented any evidence that making or using a claimed composition would require undue experimentation. The Examiner improperly bases the non-enablement finding on the fact that the specification does not include a showing of each and every possible permutation of the claimed compositions.

Moreover, the Examiner infers that such compositions were not prepared. Such an inference is improper because Applicant is not required to show in the specification actual preparation Examples for each and every composition encompassed by the claims if one of skill in the art could routinely make the claimed compositions without undue experimentation. The court in *In re Gaubert*, 524 F.2d 1222, 1226, 187 USPQ 664, 667 (CCPA 1975) stated:

To satisfy §112, the specification disclosure must be sufficiently complete to enable one of ordinary skill in the art to make the invention without undue experimentation, although the need for a minimum amount of experimentation is not fatal. . . . Enablement is the criterion, and every detail need not be set forth in the written specification if the skill in the art is such that the disclosure enables one to make the invention.

Patent Application No.: 09/340,391

While no specific working example is necessary to establish enablement, the specification must be considered in light of what it teaches to a person having skill in the art. Applicants respectfully submit that the Examiner, in his Office Action, has not satisfied his evidentiary burden. It is respectfully submitted that, in view of this evidence already in the written description coupled with the knowledge in the art at the time the application was filed, the rejection is overcome. For the foregoing reasons, it is submitted that the pending claims are believed to be enabled by the written description. Thus, reconsideration and withdrawal of the 35 U.S.C. § 112, first paragraph, rejection are respectfully requested.

THE REJECTIONS UNDER 35 U.S.C. 102(e)

The Office Action rejects claims 1-3, 5-9, 11-14 and 17 under 35 U.S.C. 102(e) as being anticipated by Bessette et al 6004569.

Carbon dioxide is an enzyme inhibitor, it is used with the instant actives and acceptable carriers (col. 14). Also shown are the instant piperonylbutoxide type synergists (col. 7).

Office Action at page 4. Applicant respectfully traverses this rejection.

In one embodiment, the claimed invention is directed to a pesticidal composition comprising (1) at least one **plant essential oil compound** (2) an **enzyme inhibitor** selected from the group consisting of piperonyl butoxide, MGK 264, and sesamex and/or (3) a **synergist** selected from the group consisting of pyrethrolone, allethrolone, chrysanthemic acid, chrysanthemyl alcohol, chrysanthemate ester, cis-jasmone, tetrahydrofurfuryl alcohol (THFA), forskolin, Lavendustin A, and PD 98059. (See claims 1 and 7). The claimed invention is also

Patent Application No.: 09/340,391

directed to a pesticidal composition comprising an **enzyme inhibitor** selected from the group consisting of piperonyl butoxide, MGK 264, and sesamex and at least one of the above-recited **synergists**. (See claim 14). On the other hand, Bessette merely discloses methods for using plant essential oil compounds as affector agents against the neurotransmitters of insects. Bessette nowhere discloses or suggests the use of plant essential oils in combination with enzyme inhibitors or synergists, as disclosed and claimed by the present invention. Thus, Applicant respectfully requests reconsideration and withdrawal of this rejection.

THE REJECTIONS UNDER 35 U.S.C. 102(b)

The Office Action rejects claims 1-4, 6-10, 12-17 under 35 U.S.C. 102(b) as being anticipated by Casida (1973). The Office Action states:

...pyrethrin, oil and synergist are insecticidal (p. 88-89). The instant flavones are also shown (p. 30-31), as are terpenols and sesquiter penes.

Office Action at page 4. Applicant respectfully traverses this rejection.

Casida merely discloses the use of pyrethrum extracts in combination with synergists. Casida nowhere discloses a pesticidal composition comprising (1) at least one **plant essential oil compound** (2) an **enzyme inhibitor** selected from the group consisting of piperonyl butoxide, MGK 264, and sesamex and/or (3) a **synergist** selected from the group consisting of pyrethrolone, allethrolone, chrysanthemic acid, chrysanthemyl alcohol, chrysanthemate ester, cis-jasmone, tetrahydrofurfuryl alcohol (THFA), forskolin, Lavendustin A, and PD 98059. (See claims 1 and 7). Moreover, Casida nowhere discloses or suggests a pesticidal composition

Patent Application No.: 09/340,391

comprising an **enzyme inhibitor** selected from the group consisting of piperonyl butoxide, MGK 264, and sesamex and at least one of the above-recited **synergists**. (See claim 14). Thus. Applicant respectfully requests reconsideration and withdrawal of this rejection.

THE REJECTIONS UNDER 35 U.S.C. 103(a)

The Office Action rejects claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Casida in view of Bessette. The Office Action states:

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize natural active compositions to use one of Casida modified with Bessette to provide acceptable application. Bessette teaches one having ordinary skill in the art would be motivated to perform this modification order to kill insects, not Mammals.

It has not clearly been established by an objective showing of some additional unusual and/or unexpected result that the concentration or administration of the particular active, carrier or adjuvant, chosen for the purpose for which it known or provides any greater level of prior art expectation as claimed. Further, no criticality, or objective showing of nonobvious or unexpected results is seen by the applicant to distinguish over the prior art.

Thus the artisan would find it obvious to prepare particular ingredient combinations, concentration and ratios of ingredients, depending upon the target species, desired number of applications, length of time for desired protection case of handling, safety to non-target species, degradation, and the use of ingredients for the functionality for which they are known to be used is not a basis for patentability. The compounds are all old, art recognized as are the recognized effects, applied by well known art recognized methods to achieve control over pests of as is well known in the art.

Office Action at page 5. Applicant respectfully traverses this rejection.

The deficiencies of Bessette and Casida in teaching the presently claimed invention are

Patent Application No.: 09/340,391

noted above. Applicant respectfully submit that one of ordinary skill in the art reading Bessette or Casida, alone or in combination, would not have been motivated to reach the claimed invention. Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. In re Fine, 837 F.2d 1071, 1075, 5 USPQ2d 1780, 1783 (Fed. Cir. 1988). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." See Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. "When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." In re Rouffet, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998) (citing In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987)). The same principle applies to invalidation. "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). Although the suggestion to combine references may flow from the nature of the problem, see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), "[d]efining the problem in terms of its solution reveals

Patent Application No.: 09/340,391

improper hindsight in the selection of the prior art relevant to obviousness," Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 880, 45 USPQ2d 1977, 1981 (Fed. Cir. 1998). Therefore, "[w]hen determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.'" In re Beattie, 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992) (quoting Lindemann, 730 F.2d at 1462, 221 USPQ at 488).

Here, the Office Action uses the present application as a blueprint. The Office Action does not discuss any specific evidence of motivation to combine, but only makes conclusory statements. "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" Dembiczak, 175 F.3d at 999, 50 USPQ2d at 1617. The Office Action provides no support for its broad conclusory statement that the claimed compositions contain compounds that are old, art recognized to achieve control over pests. In fact, nowhere does the Office Action particularly identify any suggestion, teaching, or motivation to combine the teaching of the cited references to achieve the claimed invention. The Federal Circuit has held that there must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." In re Rouffet, 149 F.3d at 1357, 47 USPQ2d at 1456; see also In re Werner Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) ("[A] rejection cannot be predicated on the mere identification . . . of individual components of claimed limitations. Rather, particular findings must be made as to the

Patent Application No.: 09/340,391

reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."). Here, no such evidence has been presented. Thus, Applicant respectfully requests reconsideration and withdrawal of this rejection.

ELECTION OF SPECIES REQUIREMENT

The Office Action requires an election of the species of plant essential oil compound, as recited in claims 5 and 11 (for which at least claims 1, 6 and 7 are generic) and a species of synergist, as recited in claim 12 (for which at least claims 7 and 14) are generic. In response, Applicant hereby elects **benzyl alcohol** and **pyrethrin** species for initial prosecution on the merits. This election is without traverse to the extent that it is understood that (a) the election of species requirements will be withdrawn upon a finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found to be patentably distinct from the elected or allowed claims.

NON-ENGLISH LANGUAGE REFERENCES CITED IN IDS

The Examiner requests English-language translations of the German-language and Belguim-language references cited in the previous Information Disclosure Statement. In response, Applicant respectfully submits that the relevance of the cited German-language and Belguim-language references is indicated on the International Search Report dated April 6, 2000, which is only what the rules require. In any event, no English-language translations are readily

Patent Application No.: 09/340,391

available to the Applicant at this time.

CONCLUSION

Early consideration and prompt allowance of the pending claims are respectfully requested. If anything could be done to place this application in condition for allowance, e.g., by **Examiner's Amendment**, Applicants respectfully request that the Examiner contact the undersigned representative at the telephone number listed below.

Please grant any extension of time deemed necessary for entry of this communication.

Please charge any deficient fees, or credit any overpayment of fees, to Deposit Account No. 50-0417.

Respectfully submitted,



Willem F. Gadiano
Registration No. 37,136

MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096
(202) 756-8000 WFG:klm
Date: April 2, 2001
Facsimile: (202) 756-8087

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this document (including any paper referred to as being attached or enclosed) is being sent to the U.S. Patent and Trademark Office via facsimile transmission on the date indicated below, with a coversheet addressed to Assistant Commissioner for Patents, U.S. Patent and Trademark Office, Washington, D.C., 20231.

Date: April 2, 2001

By: 

Willem F. Gadiano, Registration No. 37,136